

Changes the term "methadone treatment" to "opioid treatment" for purposes of the law concerning certification of opiate addiction treatment programs. Requires certification standards and certification and licensure related to opioid treatment programs. Requires the establishment of certain fees. Specifies violations and penalties. Repeals the expiration of current law requiring a methadone diversion control and oversight program.

1 SECTION 1. IC 12-7-2-135.6 IS ADDED TO THE INDIANA CODE AS A
2 NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 135.6.**
3 **"Opioid treatment program" means a program through which opioid agonist**
4 **medication is dispensed to an individual in the treatment of opiate addiction and for**
5 **which certification is required under 42 C.F.R. 8.**

6 SECTION 1. IC 12-23-1-10 IS AMENDED TO READ AS FOLLOWS
7 [EFFECTIVE JULY 1, 2008] Sec. 10. The division is the state authority primarily
8 responsible for prevention, control, treatment and rehabilitation, education, research, and
9 planning in the field of addictions. All other agencies of state and local government shall
10 cooperate with the division to assist in the performance of the division's functions.

11 **(b) The division shall cooperate with the state department of health in the**
12 **performance of the state department's functions under IC 16-25.5.**

13 SECTION 2. IC 12-23-18-0.5 IS ADDED TO THE INDIANA CODE AS A
14 NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008] **Sec. 0.5. (a)**
15 **An opioid treatment program shall not operate in Indiana unless:**

- 16 **(1) the opioid treatment program is certified by the division;**
17 **(2) after June 30, 2009, the facility in which the opioid treatment**
18 **program is operated is licensed under IC 16-25.5; and**
19 **(3) the opioid treatment program is in compliance with state and**
20 **federal law.**

21 **(b) Separate certification under this chapter is required for each location at**
22 **which an opioid treatment program is operated.**

23 SECTION 3. IC 12-23-18-1 IS AMENDED TO READ AS FOLLOWS
24 [EFFECTIVE JULY 1, 2008] Sec. 1. Subject to federal law and consistent with standard
25 medical practice in ~~methadone~~ **opioid** treatment of drug abuse, the division shall adopt
26 rules under IC 4-22-2 to establish and administer a ~~methadone~~ **an opioid treatment**

1 diversion control and oversight program to identify individuals who divert ~~controlled~~
2 ~~substances~~ **opioid treatment medications** from legitimate treatment use and to terminate
3 the ~~methadone~~ **opioid** treatment of those individuals.

4 (b) Rules adopted under subsection (a) must include provisions relating to the
5 following matters concerning ~~methadone providers~~ **opioid treatment programs** and
6 ~~individuals~~ **patients** who receive **opioid** treatment:

7 (1) Regular clinic attendance by the patient.

8 (2) Specific counseling requirements for the ~~methadone provider~~ **opioid**
9 **treatment program.**

10 (3) Serious behavior problems of the patient.

11 (4) Stable home environment of the patient.

12 (5) Safe storage capacity of **opioid** treatment medications within the
13 patient's home.

14 (6) Medically recognized testing protocols to determine legitimate **opioid**
15 treatment **medication** use.

16 (7) The ~~methadone provider's~~ **opioid treatment program's** medical
17 director and administrative staff responsibilities for preparing and
18 implementing a diversion control plan.

19 SECTION 4. IC 12-23-18-2 IS AMENDED TO READ AS FOLLOWS

20 [EFFECTIVE JULY 1, 2008] Sec. 2. Not later than February 28 of each year, each
21 ~~methadone provider~~ **opioid treatment program** must submit to the division a diversion
22 control plan ~~required under that meets the requirements of section 1(b)(7) 1~~ of this
23 chapter.

24 (b) Not later than May 1 of each year, the division shall review and approve ~~plans~~
25 **a plan** submitted under subsection (a).

26 (c) If the division denies a plan submitted under subsection (a), the ~~methadone~~
27 **provider opioid treatment program** must submit another plan not later than sixty (60)
28 days after the denial of the plan.

29 SECTION 5. IC 12-23-18-3 IS AMENDED TO READ AS FOLLOWS

30 [EFFECTIVE JULY 1, 2008] Sec. 3. By May 15 of each year, each ~~methadone provider~~

1 **opioid treatment program** shall submit to the division a ~~the fee of twenty dollars (\$20)~~
2 ~~for each nonresident patient treated by the methadone provider during established under~~
3 **section 5(a)(3) of this chapter** for the preceding calendar year.

4 (b) The fee collected under subsection (a) shall be deposited in the ~~methadone~~
5 ~~diversion control and oversight program fund. established under section 4 of this chapter.~~

6 **SECTION 6. IC 12-23-18-4 IS AMENDED TO READ AS FOLLOWS**

7 [EFFECTIVE JULY 1, 2008] Sec. 4. (a) As used in this section, "fund" means the
8 **methadone opioid treatment** diversion control and oversight program fund established
9 under subsection (b).

10 (b) The ~~methadone opioid treatment~~ diversion control and oversight program
11 fund is established to ~~administer and carry out the purposes of~~ **implement** this chapter.
12 The fund shall be administered by the division.

13 (c) The expenses of administering the fund shall be paid from money in the fund.

14 (d) The treasurer of state shall invest money in the fund in the same manner as
15 other public money may be invested.

16 (e) Money in the fund at the end of the state fiscal year does not revert to the state
17 general fund.

18 **SECTION 7. IC 12-23-18-5 IS AMENDED TO READ AS FOLLOWS**

19 [EFFECTIVE JULY 1, 2008] Sec. 5. (a) **The division shall adopt rules under**
20 **IC 4-22-2 to establish the following:**

21 **(1) Standards for operation of an opioid treatment program in**
22 **Indiana, including the following requirements:**

23 **(A) An opioid treatment program shall obtain prior**
24 **authorization from the division for any patient receiving more**
25 **than fourteen (14) days of opioid treatment medications at one**
26 **(1) time.**

27 **(B) Minimum requirements for a licensed physician's regular:**

28 **(i) physical presence in the opioid treatment facility;**

29 **and**

30 **(ii) physical evaluation and progress evaluation of each**

1 **opioid treatment program patient.**

2 **(C) Minimum staffing by licensed and unlicensed personnel.**

3 **(2) Fees to be paid by an opioid treatment program for deposit in the**
4 **fund for annual certification under this chapter.**

5 **(3) Annual fees to be paid by an opioid treatment program for deposit**
6 **in the fund for each patient served by the opioid treatment program.**

7 **The fees established under this subsection must be sufficient to pay the cost of**
8 **implementing this chapter.**

9 **(b) The division shall conduct an annual onsite visit of each ~~methadone provider~~**
10 **opioid treatment program to assess compliance with the plan approved under this**
11 **chapter.**

12 SECTION 11. IC 12-23-18-5.5, AS ADDED BY P.L.210-2007, SECTION 1, IS
13 AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008] Sec. 5.5. ~~(a)~~ The
14 division may not grant specific approval to be a new opioid treatment program. This
15 section does not apply to applications for new opioid treatment programs pending prior to
16 March 1, 2007.

17 ~~(b) This section expires December 31, 2008.~~

18 SECTION 9. IC 12-23-18-5.6 IS ADDED TO THE INDIANA CODE AS A
19 NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008] **Sec. 5.6. The**
20 **division shall establish a central registry to maintain information concerning each**
21 **patient served by an opioid treatment program.**

22 **(b) An opioid treatment program shall, at least monthly, provide to the**
23 **division information required by the division concerning patients currently served**
24 **by the opioid treatment program.**

25 **(c) Information that could be used to identify an opioid treatment program**
26 **patient and that is:**

27 **(1) contained in; or**

28 **(2) provided to the division related to;**

29 **the central registry is confidential.**

30 SECTION 10. IC 12-23-18-5.7 IS ADDED TO THE INDIANA CODE AS A

1 **NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008] Sec. 5.7. The**
2 **division shall, as part of the biennial report required under IC 12-21-5-1.5(8),**
3 **prepare and submit to the governor and the legislative council in an electronic**
4 **format under IC 5-14-6 a report concerning treatment offered by opioid treatment**
5 **programs. The report must contain the following information for each of the two (2)**
6 **previous calendar years:**

- 7 **(1) The number of opioid treatment programs in Indiana.**
- 8 **(2) The number of patients receiving opioid treatment in Indiana.**
- 9 **(3) The length of time each patient received opioid treatment and the**
10 **average length of time all patients received opioid treatment.**
- 11 **(4) The cost of each patient's opioid treatment and the average cost of**
12 **opioid treatment.**
- 13 **(5) The rehabilitation rate of patients who received opioid treatment.**
- 14 **(6) The number of patients who became addicted to opioid treatment**
15 **medication.**
- 16 **(7) The number of patients who were rehabilitated and are no longer**
17 **receiving opioid treatment.**
- 18 **(8) The number of individuals, by geographic area, who are on a**
19 **waiting list to receive opioid treatment.**
- 20 **(9) The patient information reported to the central registry**
21 **established under section 5.6 of this chapter.**

22 **(b) Each opioid treatment program in Indiana shall provide information**
23 **requested by the division for the report required by this section.**

24 **(c) Failure of a certified opioid treatment program to submit the information**
25 **required under subsection (a) may result in suspension or termination of the opioid**
26 **treatment program's certification.**

27 **(c) Information that could be used to identify an opioid treatment program**
28 **patient and that is:**

- 29 **(1) contained in; or**
- 30 **(2) provided to the division related to;**

1 the report required by this section is confidential.

2 SECTION 9. IC 16-18-2-264.3 IS ADDED TO THE INDIANA CODE AS A
3 NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 264.3.**
4 **"Opioid treatment program" means a program through which opioid agonist**
5 **medication is dispensed to an individual in the treatment of opiate addiction and for**
6 **which certification is required under 42 C.F.R. 8.**

7 SECTION 10. IC 16-25.5 IS ADDED TO THE INDIANA CODE AS A NEW
8 ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]:

9 **ARTICLE 25.5. OPIOID TREATMENT PROGRAM FACILITIES**

10 **Chapter 1. General Provisions**

11 **Sec. 1. This article applies to all facilities in which an opioid treatment**
12 **program is operated.**

13 **Sec. 2. (a) The state department and the state health commissioner shall**
14 **enforce this article.**

15 **(b) The state department or the state health commissioner may bring an**
16 **action at law or in equity to enforce this article and the circuit and superior courts**
17 **of the state have jurisdiction to compel or enforce the provisions of this article by**
18 **prohibitory or mandatory injunction.**

19 **Chapter 2. Licensure and Regulation of Opioid Treatment Program**
20 **Facilities**

21 **Sec. 1. Not later than July 1, 2009, the state department shall license and**
22 **regulate all facilities in which an opioid treatment program operates in Indiana.**

23 **Sec. 2. The state department shall adopt rules under IC 4-22-2 to do the**
24 **following concerning opioid treatment program facilities:**

25 **(1) Establish minimum licensure qualifications, including**
26 **requirements for the following:**

27 **(A) Sanitation standards.**

28 **(B) Emergency equipment and procedures.**

29 **(C) Quality assurance standards.**

30 **(D) Certification under IC 12-23-18 of the opioid treatment**

1 program operated in the facility.

2 (2) Prescribe the operating, supervision, and maintenance policies
3 concerning opioid treatment program patient records.

4 (3) Establish procedures for the issuance, renewal, denial, and
5 revocation of licenses under this chapter. The rules adopted under
6 this subsection must address the following:

7 (A) The form and content of the license.

8 (B) The collection of an annual license fee.

9 (4) Prescribe the procedures and standards for inspections.

10 (5) Establish annual licensing fees in an amount sufficient pay the cost
11 of implementing this article.

12 Sec. 3. A:

13 (1) person; or

14 (2) state, county, or local governmental unit;

15 shall obtain a license under this chapter before establishing, advertising, or
16 operating an opioid treatment program.

17 Sec. 4. (a) An applicant shall submit an application for a license on a form
18 prescribed by the state department reflecting that the applicant is:

19 (1) of reputable and responsible character; and

20 (2) able to comply with the requirements of this chapter and federal
21 law.

22 (b) An application must contain the following additional information:

23 (1) The name of the applicant.

24 (2) The location of the opioid treatment program facility.

25 (4) The name of the person responsible for the opioid treatment
26 program.

27 (5) Other information required by the state department.

28 Sec. 5. An application must be accompanied by a licensing fee at the rate
29 established by the state department under section 2 of this chapter.

30 Sec. 6. The state health commissioner may:

- 1 (1) issue a license upon an application without further evidence; or
2 (2) request additional information concerning an application and
3 conduct an investigation to determine whether a license should be
4 granted.

5 **Sec. 7. A license issued under this chapter:**

- 6 (1) expires one (1) year after the date of issuance;
7 (2) is not assignable or transferable;
8 (3) is issued only for the opioid treatment program facility premises
9 named in the application;
10 (4) must be posted in a conspicuous place in the opioid treatment
11 program facility; and
12 (5) may be renewed each year upon the payment of a renewal fee at
13 the rate established by the state department under section 2 of this
14 chapter.

15 **Sec. 8. (a)** The state department shall conduct an annual licensure inspection
16 of an opioid treatment program facility in accordance with rules adopted under this
17 chapter. The state department shall conduct all health and sanitation inspections,
18 including inspections in response to an alleged breach of this chapter. The division
19 of fire and building safety shall conduct all fire safety inspections.

20 **(b)** An employee of the state department who knowingly or intentionally
21 informs an opioid treatment program of the exact date of an unannounced
22 inspection shall be suspended without pay for five (5) days for a first offense and
23 shall be dismissed for a subsequent offense.

24 **(c)** A report of each inspection conducted under this section must be in
25 writing and sent to the opioid treatment program.

26 **(d)** A report of an inspection conducted under this section, and records
27 relating to the inspection, may not be released to the public until the conditions set
28 forth in IC 16-19-3-25 are satisfied.

29 **Chapter 3. Violations**

30 **Sec. 1.** The state health commissioner may take any of the following actions

1 based on any ground described in section 2 of this chapter:

2 (1) Issue a letter of correction.

3 (2) Issue a probationary license.

4 (3) Reinspect.

5 (4) Deny renewal of a license.

6 (5) Revoke a license.

7 (6) Impose a civil penalty in an amount not to exceed ten thousand
8 dollars (\$10,000).

9 Sec. 2. The state health commissioner may take action under section 1 of this
10 chapter based on any of the following grounds:

11 (1) Violation of this article or rules adopted under this article.

12 (2) Permitting, aiding, or abetting the commission of any illegal act in
13 an opioid treatment program facility.

14 (3) Conduct or practice found by the state health commissioner to be
15 detrimental to the welfare of an opioid treatment program patient.

16 Sec. 3. IC 4-21.5 applies to an action under this chapter.

17 Chapter 4. Penalties

18 Sec. 1. The state department shall investigate a report of an unlicensed opioid
19 treatment program facility and report the findings to the attorney general. The
20 attorney general may seek any of the following:

21 (1) An injunction in a court of jurisdiction in the county in which the
22 unlicensed opioid treatment program facility is established,
23 advertised, or operated or in the circuit or superior court of Marion
24 County.

25 (2) Relief under IC 4-21.5, including a civil penalty not to exceed
26 twenty-five thousand dollars (\$25,000) for each day of unlicensed
27 operation.

28 (3) Criminal penalties.

29 Sec. 2. A person who:

30 (1) establishes;

1 **(2) advertises the operation of; or**
2 **(3) operates;**
3 **an opioid treatment program facility that is not licensed under this article commits a**
4 **Class A misdemeanor.**

5 SECTION 8. IC 12-23-18-6 IS REPEALED [EFFECTIVE JULY 1, 2008].
6